

Identification Number: 228AABZX00136000

Controlled Medical Device – Dental Etching Agent

Multi Etchant

DO NOT REUSE NEEDLE TIPS.**[Contraindications and Prohibitions]**

- **DO NOT USE THIS PRODUCT ON PATIENTS WHO HAVE A HISTORY OF ALLERGY SUCH AS IRRITATION TO THIS PRODUCT AND/OR METHACRYLIC ACID AND SIMILAR ACIDS OR METHACRYLATE MONOMER**
- **DO NOT REUSE NEEDLE TIPS.**

[Shape, Composition and Principle]

1. Shape, Composition

This product contains the ingredients listed below.

State	Ingredients
Paste	Purified water, Phosphoric acid monomer, Thickening agents, Dye

2. Principle

The acidity of phosphate acid monomer is used to achieve cleaning and surface-roughening of natural teeth and dental restorations. Phosphoric acid monomer also modifies the quality of zirconia ceramic surfaces and enhances the bonding strength of bonding material which is subsequently applied.

[Accessory]

Needle Tip

[Intended Use and Effect/Efficacy]

This product is used for etching natural teeth and dental restorations (excepting dental technician's procedures). Also, this product is used to achieve adhesion of restorations and equipments made of zirconia ceramics.

[Instructions for Use]

1) Preparation

- (1) Turn the safety plug counter-clockwise and remove it from the syringe.
- (2) Turn the appropriate tip in a clockwise direction on the end of the syringe to attach.

2) Etching of the Tooth Substance

- (1) If the adherent surface of enamel is untreated, clean the surface in accordance with normal practice. Rinse it thoroughly with water at this point in the procedure.
- (2) Confirm that the part to be etched is thoroughly cleaned and dried. Exclusion of moisture with a rubber dam is recommended.
- (3) Apply this product and leave it for 20 sec. or more.
- (4) Rinse thoroughly with water until the color of this product has disappeared. Then dry with oil-free air.

3) Cleaning of restoration surface (Priming for zirconia)

- (1) Rinse the adherend surface thoroughly and dry.
- (2) Squeeze this product onto the adherend surface and rub lightly with a micro-brush for 20 sec. or more while applying.
- (3) Leave it for 10 sec. or more.
- (4) Rinse thoroughly with water until the color of this product has disappeared. Then dry with oil-free air.

Prior to use, carefully read the instruction manual.

[N.B.: Technical Directions and Points for Attention]

- (1) This product contains phosphoric acid monomer as an ingredient. If this product is used near the pulp, pulp capping is recommended to prevent pulpal irritation.
- (2) To prevent deterioration in quality of material properties, do not mix this product with other etching materials or dental ceramics.
- (3) Prevent the surface of teeth and restorations for adhesion from being contaminated by blood or saliva after treatment with this product. If contamination occurs, treatment with this product must be done again.
- (4) If the color of this product still remains after rinsing, remove colored area with an excavator or a round bur.

[Precautions]

[Precautions for Usage]

- (1) Be careful of accidental ingestion by patients.
- (2) Use as soon as possible after opening the package.
- (3) Since storing with the needle tip in place may cause leakage, discard the needle tip after use and store it immediately with the cap securely attached to the syringe.

[Important Basic Cautions]

- (1) Stop using this product immediately in cases of any signs of allergy such as irritation or rash appearing in patients; then advise affected patients to seek medical advice.
- (2) Operators must discontinue use if any signs of irritation or rash appear, and seek medical advice.
- (3) Take care to prevent adhesion of this product to the eyes, skin or clothing. In case of adhesion to the skin or clothing, wipe with an alcohol-soaked cotton swab immediately and wash with plenty of running water. In cases where this product gets into the eyes, wash immediately with plenty of running water and advise the affected patient to seek medical attention.
- (4) Take care to prevent adhesion of this product to the eyes, skin or clothing by wearing medical gloves and eye protection during using this product. In case of adhesion to the skin or clothing, wipe with an alcohol-soaked cotton swab immediately and wash with plenty of running water. In cases where this product gets into the eyes, wash immediately with plenty of running water and advise the affected patient to seek medical attention.

[Storage]

- Store this product at a temperature of 1-25°C.
In case where this product is not used and stored for a long period, cold storage at a temperature of 1-8°C is recommended.
- Store this product avoiding direct sunlight.
- Close the cap immediately to store after using this product.

[Expiry Date]

- ① This product must be used before the expiry date* printed on the package.
 - ② The expiry date printed on the package is based on our authentication.
 - ③ The expiry date printed on the package refers to use expiry date.
- *(e.g.; EXP YYYY-MM indicates YYYY 'year'/MM 'month' (last day) as the expiry date.)

[Package]

[Single Package]

- Multi Etchant 2ml
 - Needle tip: 5 pcs.
- Note: DO NOT REUSE NEEDLE TIPS.

[Accessory]

- Needle Tip: 10 pcs.
- Note: DO NOT REUSE NEEDLE TIPS.




1090-3 Otani, Kamibun, Kagami-cho,
Konan-shi, Kochi, 781-5451 Japan
E-mail: contact@yamakin-gold.co.jp